

**REMARKS**

Claims 1-3, 6, 15, 22, 24-27, 33, 37-39, 42, 43 and 45-56 remain pending after amendment.

**Withdrawn Rejections**

Applicants acknowledge with thanks the withdrawal of the prior rejection under 35 USC 102(b) over Day.

**Allowable Subject Matter**

Applicants acknowledge with thanks the indication of allowable subject matter of claims 3, 6, 22, 24-26, 42, 43 and 45-56. However, for the following reasons, applicants believe that all pending claims are directed to allowable subject matter.

**Rejection of Claims 1-2 under 35 USC 102(b)**

Claims 1-2 stand rejected under 35 USC 102(b) as being anticipated by Day. This rejection is respectfully traversed.

Applicants again note that claims 1, 2, 9, and 27-28 in an Official Action of April 25, 2001 were rejected under 35 USC 102(b) as being anticipated by Day '136, which corresponds to Day '522. The prior rejection was withdrawn by the Examiner. Applicants thus again question the basis for the rejection of claims 1-2 over Day '522, and request clarification by the Examiner.

Applicants nonetheless note that the reference discloses the use of an anion-binding polymer with a hydrophilic polymer to treat IBS. The reference is silent with regard to the treatment of IBD, and hence it would appear that the Examiner fails to appreciate the difference between IBS and IBD. IBS is distinguished from IBD in that there is chronic inflammation of the mucosa and sub-mucosa layers of the intestine in IBD. By contrast, IBS involves abnormally increased motility of the small and large intestines without any detectable radiological or histological evidence of organic pathology. Effective treatment of IBS is not necessarily an effective treatment of IBD.

While the anion-binding polymer and hydrophilic polymer can be administered separately, the reference states at column 6, lines 26-29 that "It is only the combination of the anion-binding polymer and hydrophilic polymer which is effective in preventing and relieving symptoms of this disease." The anion-binding polymer is present as a bile acid sequestrant, but there is no indication that, as a class, the hydrophilic polymer has any function other than for its hydrophilic activity. Exemplified hydrophilic polymers include xanthan gum, but the reference fails to suggest that the gum alone has any pharmacological effect on either IBD or IBS.

The reference also fails to exemplify the use of xanthan gum, and is also silent with respect to the use of HPMC. Moreover, the reference discloses only an oral method of administration, with the reference being silent with respect to coating or any other method of providing a delayed oral release formulation as required by claim 1.

Again, the reference contains no teaching or suggestion of the therapeutic use of xanthan gum or HPMC in the treatment of IBD (either by oral or rectal administration).

In view of the above, the rejection is without basis and should be withdrawn.

**Rejection of Claims 27 and 38 under 35 USC 102(e)**

Claims 27 and 38 stand rejected under 35 USC 102(e) as being anticipated by Sachetto. This rejection is respectfully traversed.

Applicants note that the claims were previously rejected over Slagel '115, which rejection was previously withdrawn in an Official Action of January 28, 2004. As Slagel '115 corresponds to the cited Sachetto '310 reference, applicants disagree with the decision of the Examiner to maintain this rejection.

Applicants nonetheless note that the reference discloses compositions suitable for rectal delivery or pharmaceutically active components in the treatment of conditions such as IBD, IBS and anorectal disorders. The reference discloses at Example 1 a foamable composition consisting of 2 g (or 1.9 wt.%) of the water soluble polysaccharide xanthan gum in 98g water and 1g polysorbate 80 as the sole component. It also discloses that the water soluble polysaccharide may be HMPC, and that the foam compositions may contain up to 5 wt% water soluble polysaccharide.

The reference does not, however, disclose that the composition of Example 1 (i.e., without an active agent) would be useful in the treatment of IBD, but does disclose that such foamable compositions could be used to carry an active agent for rectal administration to the rectum to treat IBD. Clearly, there is no teaching of a delayed release composition in the reference, or of a liquid enema as claimed.

The rejection is thus without basis and should be withdrawn.

**Rejection of Claim 15 under 35 USC 103(a)**

Claim 15 stands rejected under 35 USC 103(a) as being unpatentable over Day.

This rejection is respectfully traversed.

Claim 15 depends from claim 1 which has been demonstrated to patentably distinguish over the cited reference.

The rejection is thus without basis and should be withdrawn.

**Rejection of claim 39 under 35 USC 103(a)**

Claim 39 stands rejected under 35 USC 103(a) as being unpatentable over Sachetto '310. This rejection is respectfully traversed.


Claim 39 depends from claim 27, which claim has been shown to patentably distinguish over the cited reference. Given the distinctions that exist between the claimed invention and the cited reference, the instant rejection is also without basis and should be withdrawn.

In view of the above, it is believed that the application is now in condition for allowance, and an early indication of same earnestly is solicited.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By   
James W. Hellwege, #28,808  
P.O. Box 747  
Falls Church, VA 22040-0747  
(703) 205-8000

JWH/sh  
3920-0103P